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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,496	03/28/2001	Erik Labergerie	3-1032-157	4780

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EXAMINER
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JOYNES, ROBERT M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/18/2002 //

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/819,496

Applicant(s)

LABERGERIE ET AL.

Examiner

Robert M. Joynes

Art Unit

1615

-- **Th MAILING DATE of this communication app ars on the cover sh t with th correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 10-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-18 is/are rejected.
- 7) ☒ Claim(s) 13 and 14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt is acknowledged of Applicants' Amendment filed on January 4, 2002.

#### ***Claim Objections***

Claims 13 and 14 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 13 is a process claim that depends upon a product claim in Claim 10. Claim 13 recites a "process for preparing pulverulent mannitol according to Claim 10." Claim 10 is drawn to a product, not a process. Therefore, Claim 13 fails to further limit the subject matter of the previous claim. It is suggested that applicant amend or cancel the claim to place it in proper dependent form.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and

Art Unit: 1615

Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 10 and 11 recite the broad recitation broad limitation for characteristics of the mannitol, and the claim also recites narrower, more preferable ranges which is the narrower statement of the range/limitation.

Claim 15 and 17 recite the phrase "in particular." It unclear what applicant intends to convey by the use of this phrase when describing the form of the mannitol.

Claim 10 recites the specific testing procedures used to determine the packed density of the mannitol. It is unclear whether or not the "packed density" equivalent to the "packed bulk density" referred to in the operating instructions. Further, it is unclear whether the tests referenced was known as a standard measuring test at the time the invention is made. It is suggested that applicants maintain continuity between terms in the claims and in the referenced operating instructions. Further, clarification on the year the instructions were published would show whether the powder tests in the instructions were standard procedures at the time the invention was made.

***Claim Rejections - 35 USC § 102***

Art Unit: 1615

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-18 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,573,777 to Serpelloni *et al.*. Serpelloni *et al.* teach a relatively pure pulverulent mannitol, having a moderate and non-excessive friability, a low density, and a particle size of between 100 and 200 microns, wherein less than 30% of the particles have a size less than 75 microns (abstract). Serpelloni *et al.* also teach that the mannitol richness of their composition will be at least 90%, most preferentially greater than 98.5% (c 6, l 34-45). Serpelloni *et al.* also teach that the pulverulent mannitol can be formed through wet granulation (c 8, l 37-38). Lastly, Serpelloni *et al.* teach that the mannitol of their invention can be used as a sweetening agent, texturizing agent, or additive excipient or vehicle, in particular in the food and pharmaceutical fields. Therefore, the teachings of Serpelloni *et al.* anticipate the limitations of applicant's instant claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Serpelloni *et al.*. Serpelloni *et al.* are described above as teaching a pulverulent mannitol composition, with moderate and non-excessive friability, low density, and less than 30% of particles with a size less than 75 microns. Serpelloni *et al.* do not disclose density in the same units as applicant, nor does Serpelloni *et al.* disclose a specific flow factor. However, the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). It is the position of the examiner that one of ordinary skill in the art would look to the teachings of Serpelloni *et al.* in order to produce a pulverulent mannitol composition for use as a pharmaceutical excipient. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Response to Arguments***

Applicant's arguments filed January 4, 2002 have been fully considered but they are not persuasive. Applicant argues that the reference cited in the Office Action dated August 14, 2001 teaches an additional step in the process of making. Further,

Art Unit: 1615

Applicants argue that the packed densities of the two inventions are remarkably different.

Examiner recognizes that the reference teaches the step of atomization the solution of mannitol and water. However, applicant uses comprising language in the claims, which allows for other components to be present in the composition. The expression " comprising " permits the presence of other ingredients or steps in the process and does not preclude the presence of other steps in the procedure, ingredients, active or inactive, even in major amounts. See *Moleculon Research Corporation v CBS, Inc* 229 USPQ 805; *In re Baxter* 210 USPQ 795, 803.

Applicant's argument regarding the packed density is also found to be unpersuasive. The instant claims recite a packed density of between 0.65 and 0.85 g/ml. The reference teaches a packed density of just under 0.60 g/ml. The criticality of such a small difference is unclear. Any distinction is a matter of degree and not of kind.

The Examiner would like to further draw applicant's attention to the reference cited. All of the characteristics of the mannitol contemplated in the instant application were also contemplated and recognized by the cited reference. The reference recognized that friability, flow factors, density and particle size are all factors need to be improved upon in the art of pharmaceutical excipients (Col. 1, line 47 – Col. 4, line 30). More specifically, the reference recognized a need for an excipient that would simultaneously have the advantages of being non-cariogenic and non-hygroscopic, of possessing good flow and dissolution properties and of not being the source of dust or of explosions in production or packaging plants (Col. 4, lines 16-30). To do so, the

Art Unit: 1615

reference teaches the implementation of relatively pure mannitol and to modify its physical characteristics by employing an appropriate process so that it simultaneously has a moderate and not excessive friability, a centered particle size free of fine particles and a structure of little density (Col. 4, lines 22-30). The Examiner sees little difference between the instant claims and the teachings of the cited reference.

### ***Conclusion***

Due to the new grounds for rejection under 35 U.S.C. 112 and new Claim Objections, this Action is deemed Non-Final.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Monday through Friday 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

**THURMAN K. PAGE**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**